In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-1772V

UNPUBLISHED

SILVIA BAVLI, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: April 15, 2024 Special Processing Unit (SPU); Influenza Vaccine; Guillain-Barre Syndrome (GBS); Vaccine Act Entitlement;

Andrew Donald Downing, Van Cott & Talamante, PLLC, Phoenix, AZ , for Petitioner.

Joseph Adam Lewis, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On August 27, 2021, Silvia Bavli filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she received an influenza ("flu") vaccine on December 18, 2019, and thereafter suffered Guillain-Barré syndrome ("GBS"). Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, this claim is hereby **DISMISSED**.

[1] Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

After the claim's initiation, Respondent filed a Rule 4(c) Report opposing compensation. Respondent's Rule 4(c) Report (ECF No. 21) at 9-12. Petitioner thereafter filed a motion for a ruling on the record with regard to entitlement on December 16, 2022. Motion for Ruling on the Record ("Mot."), ECF No. 27. Petitioner argues that she meets the Table requirements for GBS following a flu vaccine, or in the alternative that her injury was caused-in-fact by the flu vaccine. Mot. at 26-30.

Respondent filed a response on December 30, 2022, arguing that Petitioner has not established onset of her injury occurred within forty-two days of vaccination administration, thus preventing her from succeeding on a flu vaccine-GBS Table claim, and also that she could not otherwise prove causation-in-fact. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 28, at 10-16. Petitioner filed a reply on January 3, 2023, addressing Respondent's arguments. Petitioner's Reply in Support of her Motion for Ruling on the Record ("Reply"), ECF No. 29.

II. Petitioner's Medical Records

Petitioner's prior history includes bloody stool and rectal bleeding, resulting in referral to gastrointestinal specialist. Ex. 3 at 4-5. Further, Petitioner routinely saw a gastroenterologist for colonoscopies, and reported intermittent changes in her bowel habits since at least 2016. Ex. 7 at 8. A colonoscopy in 2013 revealed diverticulitis, and another in 2017 revealed tubular adenoma. *Id.* at 24; Ex. 3 at 29. Additionally, Petitioner reported bloody stools on September 18, 2019. Ex. 3 at 5.

Petitioner received a flu vaccine and a Shingrix vaccine on December 18, 2019. Ex. 2 at 2. There is no contemporaneous medical record evidence of any immediate vaccine reaction. Petitioner's next medical treatment visit occurred on February 3, 2020, when she saw Dr. Rimma Shaposhnikov, a gastroenterologist, with complaints of diarrhea, described as urgency and "accident x 2". Ex. 7 at 38-39. Dr. Shaposhnikov noted that Petitioner had a family history of colon cancer and referred her for a colonoscopy. *Id.* at 45. After the visit, Petitioner's assessment was "Diarrhea of presumed infections origin." Ex. 2 at 4.

Petitioner subsequently saw Dr. Peter-Brian Andersson, a neurologist, on February 28, 2020. Petitioner reported sudden episodes of stool incontinence that occurred on January 30, 2020, but had experienced no similar issues "before or since." Ex. 10 at 3. Dr. Andersson also noted that Petitioner had "contracted a nonspecific upper respiratory tract injection without fever but some cough and nasal discharge that had

essentially resolved" in the beginning of February. *Id.* And she developed a runny nose after returning from a cruise on February 25, 2020, that was improving. *Id.* Further, she reported progressing numbness in her fingers and toes beginning on February 26, 2020, parenthesis in her arms when she bent forward, impaired balance, and "twisting pain in the left leg at night." *Id.* An examination revealed Petitioner's reflexes were absent, her gait was abnormal and "mildly unsteady". *Id.* at 5-6. Following electromyogram and nerve condition studies, Dr. Andersson concluded the results were abnormal and provided support for GBS. *Id.* at 133 He also noted the testing "was done at day 3 after symptom onset." *Id.*

On February 28, 2020, Petitioner went to the Tarzana Medical Center emergency room for weakness and difficulty walking over the past three days. Ex. 14 at 4. She also reported that she had an upper respiratory infection and still had a cough following a three-week cruise. *Id.* The treating physician noted that Petitioner had weakness in her lower extremities, but had a normal gait and coordination. *Id.* at 5-6.

Petitioner was admitted to the hospital from February 28 to March 3, 2020. Ex. 14 at 8. She underwent an MRI, which showed mild cortical and deep atrophy, along with evidence of ethmoid sinus disease. *Id.* at 82. She also tested positive for influenza. *Id.* at 64, 72. She received five doses of intravenous immunoglobulin, gabapentin, Norco, and morphine. *Id.* at 10, 17, 53. Following a variety of testing, she was assessed with GBS "post viral". Ex. 14 at 72. She was discharged on March 3 having improved, with the assessment again stating GBS "post viral. Numbness of lower extremities, much improved". *Id.* at 10.

Petitioner had a follow-up with her primary care physician on March 5, 2020, with reports of improving strength, but painful neuropathy in the evenings. Ex. 7 at 46. However, by March 16, 2020, Petitioner stated to Dr. Andersson that she felt "almost back to normal" with no fatigue or new complaints. Ex. 10 at 11. She also reported "two sudden episodes of stool incontinence with relatively loose stool" on January 30 that she has not had "before or since." *Id.* Dr. Andersson wrote that Petitioner made a "[r]emarkable recovery" and recommended stretching and exercise. *Id.* at 14.

On March 31, 2020, Petitioner reported new complaints to Dr. Andersson, including intermittent numbness in her extremities when walking. Ex. 10 at 15. An examination showed Petitioner's movements and gait were normal. *Id.* at 17. She continued to report congoing pain, paresthesias, numbness, and cognitive symptoms throughout April, May, and June of 2020. Ex. 10 at 21, 22, 26, 28; Ex. 7 at 60.

On August 24, 2020, Petitioner had an appointment at Rheumatology Associates. Ex. 4 at 38. The records state that she was diagnosed with GBS in February, and she had two episodes of bowel incontinence in January and February. *Id.*

Petitioner had a virtual office visit with Dr. Jeffrey Galpin, an infectious disease doctor, on September 4, 2020. He opined that "her symptoms may also have been caused by Guillain-Barre that was triggered by a type of flu." Ex. 8 at 163-66.

Dr. Andersson submitted a letter on March 19, 2021, stating that, to a degree of "reasonable medical probability", Petitioner's GBS developed after Petitioner's flu vaccine. Ex. 11 at 1. He notes that Petitioner's case is unusual for the bladder and bowel symptomatology that developed twelve days post vaccination, and occurred intermittently until February 11. *Id.* at 3. Further, Dr. Andersson states that "[b]ladder involvement has been described in Guillain Barre Syndrome, and bowel incontinence in polyneuropathy", and he does not see the "sphincter involvement as indicating an alternative disease… because of the negative work-up and no other disease diagnosis…." *Id.* at 3. He also states that Petitioner had GBS because she met the diagnostic criteria, citing symptomology present in February and no features that exclude the diagnosis, including the transient bowel and bladder dysfunction of "unclear cause antedating the typical [GBS] motor and sensory symptoms and signs." *Id.* at 3-4.

Petitioner submitted an affidavit in support of her claim on June 21, 2021. Ex. 1. Petitioner states that she received a flu vaccine on December 18, 2019, and experienced three to four episodes of bladder incontinence through period of Christmas and New Years of 2019, and feelings of fatigue. *Id.* She also had six episodes of fecal incontinence and progressive fatigue in January of 2020. *Id.* With regard to neurological symptoms, Petitioner states that she began having tingling sensations and balance issues on February 25, 2020. *Id.* at 2.

III. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y*

of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, he or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, GBS is compensable if it manifests within 3-42 days (not less than three days and not more than 42 days) of the administration of an influenza vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). (Further criteria for establishing a GBS Table Injury case be found under the accompanying qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(15)).

Cases alleging a Table GBS injury have often been dismissed for failure to establish proper onset. *See, e.g.*, *Randolph v. Sec'y of Health & Human Servs.*, No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (finding GBS onset at the earliest occurred 76 days post-vaccination, "well outside the 3-42-day window set by the Table for a flu-GBS claim"); *Upton v. Sec'y of Health & Human Servs.*, No. 18-1783V, 2020 WL 6146058, at *2-3 (Fed. Cl. Spec. Mstr. Sept. 24, 2020) (finding the petitioner did

[3] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

not establish the onset of her GBS within the 3-42 day time frame prescribed and thus did not establish a Table Injury). But even non-table claims have been dismissed when onset occurs significantly outside the 42-day limit. *See, e.g.*, *Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322, at *33 (Fed. Cl. Mar. 15, 2019), *review denied*, 144 Fed. Cl. 378 (2019) (finding that the onset of the petitioner's GBS occurred eleven to twelve weeks after her vaccination, which was beyond the six- to eight-week medically appropriate timeframe for the occurrence of vaccine-induced GBS); *Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (finding eight weeks (56 days) is the longest reasonable timeframe for a flu vaccine/GBS injury).

IV. Analysis

Petitioner asserts that she is entitled to compensation because she has established a Table injury. Mot. at 26-28. Specifically, Petitioner submits that the onset of her GBS first manifested as urinary incontinence throughout the period of Christmas and New Years, with six episodes of bowel incontinence between January 8 and January 28, 2020. *Id.* at 26-27. In support, Petitioner submitted an article wherein an individual's incontinence occurred in conjunction with, and even several weeks after, sudden onset of weakness GBS. Ex. 15 at 1, Sandeep Kumar Kar *et al.*, Faecal Incontinence in Gullain-Barre Syndrome with Bulbar Palsy-A Case Report with Review of Literature, J. Clin. Exp. Cardiolog 2016, 7:2 ("Kar").

Respondent maintains in response that Petitioner has not met the Table requirements because the onset of her GBS occurred seventy days after her flu vaccine, well outside the 42-day period set forth in the Table. Further, Petitioner's incontinence was not linked to Petitioner's flu vaccine, and any attempt to do so is contradicted by the contemporaneous records. Opp. at 12-13.

a. Petitioner Has Not Established a Table Claim

The following factual findings are made after a complete and thorough review of the record, including all medical records, affidavits, and all other additional evidence and filings from the parties.[4]

Petitioner alleges she suffered a Table GBS injury following a flu vaccine administered on December 18, 2019. Mot. at 26-28. Petitioner would need to show her

[4] Though every document is not specifically referenced in this ruling, the complete record was reviewed and considered. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision.").

symptoms began within 42 days of her vaccination, or before January 29, 2020, to succeed in establishing the Table onset element However, contemporaneous medical records preponderantly establish that the initial symptoms of Petitioner's GBS did not occur until 71 days after her vaccination, when Petitioner presented to the hospital reporting progressing numbness in her fingers and toes that started February 26, 2020. Ex. 10 at 3. Further, Petitioner's contemporaneous medical records consistently document that her symptoms did not begin until February of 2020. *See*, *e.g.*,Ex. 14 at 3 (record from February 28, 2020 stating Petitioner's condition included weakness and difficulty walking over the past three days).

Petitioner attempts to fit her circumstances into the Table timeframe, arguing that her first symptoms began with incontinence in the December 2019 to January 2020 period. Mot. at 27, citing Petitioner's affidavit, Ex. 1. However, the contemporaneous medical records make no mention of the bladder incontinence Petitioner assets occurred in late December and early January. Petitioner also argues that a series of fecal incontinence episodes starting on January 8, 2020, were the first signs of her GBS. Mot. at 27. Again, the medical records contradict this timeline. The first medical record describing diarrhea is from February 3, 2020, stating that she experienced two accidents, and was assessed with diarrhea of "presumed infections origin." Ex. 7 at 38-39; *see also* Ex. 4 at 38 (record from August 24, 2020 stating that Petitioner had two episodes of bowel incontinence in January and February of 2020). She also reported to her neurologist on February 28, 2020, that she experienced sudden episodes of stool incontinence on January 30, 2020, and had no similar issues "before or since," contradicting her claim that six episodes of incontinence and progressive fatigue occurred in January of 2020. Ex. 10 at 3.

Petitioner argues that the incontinence has been linked to GBS, citing a case study involving a single individual. Kar; Reply at 3-4. However, there are significant differences between the individual described in Kar and Petitioner's symptoms. First, Kar notes incontinence and diarrhea occurred three weeks *after* sudden onset of weakness. *Id.* at 1. However, here, the neurological symptoms associated with GBS did not occur concurrently with Petitioner's incontinence, and did not even manifest until approximately one month later. And in any event, as noted above, Petitioner's symptoms allegations are not corroborated by record evidence.

Additionally, Petitioner relies on the letter from Dr. Andersson, who concluded that Petitioner's GBS was caused by her flu vaccination. Ex. 11, Reply at 3. However, Dr. Andersson also concluded that Petitioner's bowl and bladder symptoms were of "unclear cause antedating the typical [GBS] motor and sensory symptoms and signs." *Id.* at 4. Further, he stated that incontinence has been described in polyneuropathy, but "its

relationship to this case is obscure and this symptom had resolved before development of the limb weakness." Moreover, Dr. Andersson explained that Petitioner's GBS began *after* her bladder and bowel symptoms, starting that onset of her GBS symptoms was on February 25, 2020. *Id.* at 2.

When the record is read in its entirety, the evidence of a purportedly earlier onset is outweighed by the contemporary evidence. Moreover, even if I gave Petitioner's assertions about an earlier onset more weight, they would describe a GBS course inconsistent with what is known about the illness. GBS is, in the vast majority of cases, an acute and monophasic condition. It is not known to present with bouts of incontinence prior to neurological symptoms that remains subacute for weeks or months. *Chinea*, 2019 WL 1873322, at *31, 33. It is not preponderantly likely that Petitioner would have experienced GBS onset in the form she described in January, only to manifest acutely at the end of February – with all of these symptomatic events occurring a fairly long time after the purported instigating event of vaccination.

Thus, a preponderance of evidence best supports the conclusion that the onset of Petitioner's GBS occurred 71 days after her flu vaccination. This is well outside the 42-day window set forth in the Table, and therefore Petitioner has not met a criterion needed to establish a Table claim.[5]

b. Petitioner Has Not Established a Causation-In-Fact Claim

To proceed on a theory of causation-in-fact, a petitioner must show by a preponderance of the evidence that "a vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. All three prongs must be met. *Id.* (providing a petitioner must satisfy all three prongs).

The record preponderantly establishes that Petitioner's GBS began no sooner than 71 days post vaccination, outside the *longest timeframe* (eight weeks) generally accepted for a similar non-Table claim recognized in the Program. *See, e.g.*, *Barone*, 2014 WL 6834557, at *13. Such a delay in manifestation of her symptoms is too lengthy to be considered "medically acceptable to infer causation-in-fact." *See de Bazan v. Sec'y of Health & Human Servs. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir.

[5] Respondent also argues that he has established, by preponderant evidence, that the injury was caused by factors unrelated to the vaccine. Resp. Res. at 7. Namely, that Petitioner's gastrointestinal illness was the cause of her GBS. *Id.* Because I have determined that Petitioner has not established a Table injury, it is unnecessary to address Respondent's argument.

2008). Indeed, it is arguably the case that onsets that exceed the 3-42 day timeframe are suspect – but the Program has in some specific circumstances gone beyond that period.

Here, the onset (coupled with symptoms that have not convincingly been demonstrated to be GBS-specific) is just too far from the date of vaccination to reasonably associate the two. To find otherwise would be to embrace a *post hoc ergo propter hoc* kind of reasoning not accepted for causation cases. *Bulman v. Sec'y of Health & Hum. Servs.*, No. 19-1217V, 2023 WL 5844348, at *14 (Fed. Cl. Aug. 16, 2023) ("Program case law recognizes that not all post-vaccination injuries are vaccine-caused simply because vaccination predated them."); *see also Galindo v. Sec'y of Health & Hum. Servs*, No. 16-203V, 2019 WL 2419552, at *20 (Fed. Cl. Spec. Mstr. May 14, 2019) (citing *U.S. Steel Group v. United States*, 96 F. 3d 1352, 1358 (Fed Cir. 1996) ("[b]ut to claim that the temporal link between these events proves that they are casually related is simply to repeat the ancient fallacy: *post hoc ergo propter hoc*"). Petitioner has not otherwise persuasively established circumstances in which such an unusually lengthy post-vaccination onset could still be deemed medically acceptable.

V. Conclusion

The evidentiary record does not preponderantly support Petitioner's contention that the flu vaccine she received in December 2019 caused her GBS in the timeframe at issue, does not support the allegation that she suffered a Table Claim, and would not support allegations that her GBS was caused-in-fact by the flu vaccine.

Petitioner has not established entitlement to a damages award, and therefore I must **DISMISS** her claim in its entirety. **The Clerk of Court shall enter judgment accordingly.**[6]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[6] If Petitioner wishes to bring a civil action, he must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."